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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,646	10/27/2003	Ko-Pen Wang	2607-0003	8915

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EXAMINER

APANIUS, MICHAEL

ART UNIT PAPER NUMBER

3736

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,646

Applicant(s)

WANG, KO-PEN

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-19 and 24 is/are rejected.
- 7) ☒ Claim(s) 9-12 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed on 5/12/2006. The amendments to claims 1, 7, 8, 13-19, 24 and 25; the cancellation of claims 20-23; and the amendments to the specification. Currently, claims 1-19, 24 and 25 are pending.

Claim Objections

2. Claims 1-12 are objected to because of the following informalities. At claim 1, line 10, it appears that "the distal end" should be --a distal end--. Furthermore, it appears that --region-- or --portion-- should be inserted after "distal end" at lines 10, 13 and 15 of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8, 13-19 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (US 4,966,162).

5. In regards to claim 1, Wang discloses a medical device (figure 13; column 11, line 40 - column 12, line 47), comprising: a flexible outer tubular member (210) having proximal and distal ends; a flexible inner member slidably received within the flexible

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outer tubular member, the flexible inner member comprising a stylet (218) adjacent the proximal end of the outer tubular member, a first spring section (distal half of 302) having proximal and distal ends and being oriented adjacent the distal end of the outer tubular member, and a second spring section (proximal half of 302 including multiple gaps 318) coupled to the stylet and the proximal end of the first spring section; and a hollow needle member (304) coupled to the distal end of the first spring section, wherein the device has a retracted position wherein the needle member is retractably housed within the outer tubular member and a distal end of the device is flexible, a first extended position wherein the needle member is at least partially deployed beyond the distal end of the outer tubular member and the second spring section is in an uncompressed state and the distal end of the device is less flexible (because the distal end is now occupied by the needles which provide greater rigidity) than is achieved in the retracted position, and a second extended position wherein the second spring section is in a compressed state and the distal end of the device is less flexible (because the spring is compressed) than in the first extended position. Note that the second spring section will not be compressed until a limiting member (312) contacts a hard tip (222). Therefore, the needle member can be partially deployed (first extended position) before the limiting member contacts the hard tip without compression of the second spring section. Upon further deployment of the needle member in the distal direction to the second extended position, the spring will begin to compress when the limiting member (312) begins to contact the hard tip (222).

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6. In regards to claim 2, the device has a hard tip (222) rigidly fixed to the distal end of the outer tubular member, the tip including a bearing surface on the proximal end thereof.

7. In regards to claim 3, the needle member includes a limiting member (312) rigidly secured at a point along the length of the needle member and contacting the bearing surface of the tip member in the first and second extended positions

8. In regards to claim 4, the device has a locking member (the threads of 124) securing the inner member into a contacting relationship with the bearing surface to prevent retractable movement of the needle member when in the second extended position.

9. In regards to claim 5, the first spring section comprises a first wavelength and the second spring section comprises a second wavelength (across multiple gaps 318) greater than the first wavelength in the retracted and first extended positions.

10. In regards to claim 6, the second spring section comprises a third wavelength (when the second spring section is compressed) in the second extended position, the third wavelength being less than the second wavelength.

11. In regards to claim 7, the device has a stop member (158) positioned within the flexible outer tubular member to control the amount of retraction of the needle member.

12. In regards to claim 8, the stop member comprises a crimped band (column 5, lines 32-35).

13. In regards to claims 13-19 and 24, the limitations are similarly met as stated above in regards to claims 1-8.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

16. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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17. Claims 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/693,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claim recites all of the limitations of the instant claims and therefore “anticipates” the instant claims. The copending claim recites an elongated outer flexible hollow catheter (outer tubular member in claim 27), an elongated member (elongated stylet in claim 27), a helically wound wire member (spring member in claim 27), wherein the wire member has a proximal region having a first wavelength, and a distal region having a second wavelength normally smaller than the first wavelength (claim 34); and a sampling member (outer hollow needle member in claim 27); wherein device has a first extended position (claim 28). Note that claims 27, 28 and 34 are all parent claims of copending claim 35.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

19. Claims 9-12 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. The following is a statement of reasons for the indication of allowable subject matter: no prior art of record teaches or fairly suggests a stylet/elongated member

attached to the spring that is also capable of extending through an inner volume of the spring or into the hollow needle member/sampling member.

Response to Arguments

21. Applicant's argument that the stylet (308) is not connected a proximal portion of the spring was persuasive. Therefore, a new interpretation of the reference is stated in the rejections above wherein the stylet is considered element 218.

22. The Examiner acknowledges Applicant's argument that the gaps serve as passageways for the fluid and vacuum to flow and should not be closed. Even though the gaps of the patent are intended to provide passageways, the gaps also provide a portion of the spring with a larger wavelength. During use of the patented device, the gaps may be compressed slightly to provide a smaller wavelength than when the spring is uncompressed. The gaps need not be fully closed when the spring is compressed.

23. In response to the Applicant's argument that there is no suggestion for dividing the spring into halves, the Examiner respectfully submits that any spring can arbitrarily be divided into separate regions, sections, or halves. A division of a spring into regions, sections, or halves does not require that the spring have different characteristics in the different regions, sections, or halves.

24. Applicant argues that the patent does not discuss, disclose or suggest a variety of levels of flexibility, the concept of having the distal end of the device be changeably from being very flexible and then rigid, nor how one can employ a variety of spring conditions to provide those varying levels of flexibility, nor the use of an inner stylet to

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work with the springs. However, column 9, lines 21-50 states that varying the flexibility of the spring is used to provide a rigid connection when needed to obtain a sample and to provide high flexibility when maneuvering the device through sharp turns. The distal end of the device is more flexible when the device is in the retracted position and the distal end becomes less flexible when the device is moved into the first or second extended positions. The patent discloses an inner stylet connected with the spring as noted above.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,329,980 discloses a sheath for an endoscope wherein the flexibility is controlled by compression of a spring in the sheath. US 4,693,257 discloses a needle aspiration biopsy device. US 5,056,529 discloses an apparatus for performing a transbroncheal biopsy. US 5,601,588 discloses an endoscopic puncture needle.


26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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